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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,542	03/20/2001	Maximilian Angel	51280	9058

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Herbert B. Keil
KEIL & WEINKAUF
1101 Connecticut Ave., N.W.
Washington, DC 20036

EXAMINER

JOYNES, ROBERT M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,542

Applicant(s)

ANGEL ET AL.

Examiner

Robert M. Joynes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' Information Disclosure Statements file on March 20, 2001 and May 29, 2001, Preliminary Amendment filed on March 20, 2001 and Priority Papers filed on March 20, 2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 12 and 15 recite the phrase "where appropriate" to convey certain additional components can be added to the capsule. It is unclear when or how these additional components are appropriate.

Claims 1, 14, 15 and 19 recite the term "conventional" and "customary" to describe constituents or pharmaceutical coating processes. It is unclear what applicant is trying to convey by using the term "conventional."

Claims 7-9 recite ratios of amounts but it is unclear what amounts those ratios refer to in the invention.

Claim 10 recites that the polymers are crosslinked by a "polymer-analogous reaction." It is unclear what the applicants are trying to convey by referring to a polymer-analogous reaction.

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Claim 11 recites salts of multiply charged cations as a possible crosslinker. It is unclear what a salt of a multiply charged cation is in this context.

Claims 20-22 provides for the use of soft capsules, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 20-22 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Regarding claim 6, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 6 and 13 the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 14, 15 and 18 recite the limitation "the shell" in line 2, line 1 and line1, respectively. There is insufficient antecedent basis for this limitation in the claim.

Claims 7-9 recite the limitation "the ratios of amounts" in Line 1 of the claims. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the subsequent crosslinking" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claims 6, 11, 13 and 14 are unclear because both claims are in improper Markush format. The proper Markush format is the expression "selected from the group *consisting of*" and the use of the terms "and" OR "or" only before the last Markush member. It is unclear whether one item of the group is chosen or all items must be included. It is suggested to amend the claims to reflect proper Markush format.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 2-4 recites the broad recitation of ranges for the letter variables for the structures in the respective claims, and the claim also recites narrower ranges with in parentheses which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-10 12, 13 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Harreus et al. (US 3984494). Harreus et al. teach a capsule comprising polyvinyl alcohol, vinyl acetate and polyethylene oxide (Col. 1, lines 38-47; Col. 2, Example 1; Col. 3, Claim 1). The polyvinyl alcohol is present in the capsule in amounts from 20% to 98% (Col. 1, lines 38-47; Col. 3, Claim 1). The vinyl acetate is present in the capsule in amounts from 1% to 50% (Col. 1, lines 38-47; Col. 3, Claim 1). The polyethylene oxide is present in the composition in amounts from 1% to 50% (Col. 1, lines 38-47; Col. 3, Claim 1). The capsule further comprises a plasticizer (Col. 1, lines 58-68). The plasticizer is glycerol, sorbitol, cane sugar or propylene glycol (Col. 1, lines 58-68).

Harreus et al. teach the capsule limitations of instant Claims 1-8, 10-13, 16 and 18-20. Therefore, Harreus et al anticipate Claims 1-8, 10-13, 16 and 18-20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-10 12, 13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harreus et al. (US 3984494). The teachings of Harreus are discussed above. Harreus does not teach the exact percentages of the recited components of the instant claims.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amounts of the polymers in the capsule.

One of ordinary skill in the art would have been motivated to do this to prepare capsules of differing hardness (Col. 2, lines 12-24).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 11, 14, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harreus et al. in view of Cade et al. (WO 98/27151). The teachings of Harreus are discussed above. Harreus does not expressly teach the crosslinking agents recited in Claim 14. Harreus further does not expressly teach the constituents recited in Claim 17. Still further, Harreus does not expressly teach that the capsules are coated with a gastric resistant polymer.

Cade et al. teach a cross-linked polymer capsule comprising a water-soluble cellulose ether, a hydrocolloid and a sequestering agent (Page 9, Claim 1). The sequestering agent can be boric acid (Page 3, lines 16-20). The capsule further comprises a coloring agent (Page 4, lines 12-21). Cade et al. teach that the capsule can be coated with a suitable coating agent (Page 4, line 22 – Page 5, line 2). The coating agent can be cellulose acetate phthalate, polyvinyl acetate phthalate, methacrylic acid polymers, hypromellose phthalate, hydroxypropylmethyl cellulose phthalate or hydroxyalkyl methyl cellulose phthalate (Page 4, line 22 – Page 5, line 2).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include in a polymeric capsule composition a sequestering agent, coloring agent and gastric resistant coating.

One of ordinary skill in the art would have been motivated to do this to prepare a capsule with various color schemes for identification of active ingredient purposes. One of ordinary skill in the art would be motivated to add a coating to the capsule to prepare capsules of differing release profiles, for example a sustained released capsule.

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Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harreus et al. in view of Boeckh et al. (US 5972508). The teachings of Harreus are discussed above. Harreus does not expressly teach that the monomers recited in instant Claim 9.

Boeckh et al. teach that known monomers for microcapsules are acrylic and methacrylic esters of monohydric C₁-C₂₄ alcohols (Col. 3, line 59 – Col. 4, line 22).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include any suitable monomer to the capsule composition.

One of ordinary skill in the art would have been motivated to do this to prepare a controlled release capsule.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday through Friday 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
March 8, 2002

THURMAN K. PAGE
SUPERVISORY/PATENT EXAMINER
TECHNOLOGY CENTER 1600